Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

"The effects of palliative care on anxious thoughts and life expectancy in patients with heart failure

Protocol summary

Study aim
Determining the effect of palliative care on anxiety thoughts and life expectancy in heart failure patients referred to the heart departments of hospitals affiliated to Kerman University of Medical Sciences in 2023

Design
A clinical trial with a control group, on 80 patients with heart failure, it will use for randomization using the block randomization method.

Settings and conduct
This study will be conducted on heart failure patients referred to heart departments of hospitals affiliated to Kerman University of Medical Sciences. It has 2 control and intervention groups.The intervention group will receive the palliative care protocol that includes 8 sessions, and the control group will receive only routine care. Patients with heart failure will be selected in the accessible way and then will be placed in 2 control and intervention groups by block randomization.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Age over 18 years-Having heart failure-Ability to understand and speak Persian-Ability to answer questionnaire questions exclusion criteria: No participation in more than two training sessions, No answering more than a third of the questions-Sensory disorders such as vision and hearing problems that affect learning

Intervention groups
The intervention group will receive the educational protocol along with routine care. The educational protocol of the study includes a two-week palliative care program in the form of one-hour training sessions, four times a week. The control group will receive only the routine care of heart failure patients.

Main outcome variables
The score obtained from Schneider's life expectancy questionnaire The score obtained from the Wells Anxiety Thoughts Questionnaire

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20231223060506N1**
Registration date: **2024-01-21, 1402/11/01**
Registration timing: **prospective**

Last update: **2024-01-21, 1402/11/01**
Update count: **0**

Registration date
2024-01-21, 1402/11/01

Registrant information
Name
Rezvan Askarpour
Name of organization / entity
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Iran (Islamic Republic of)
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Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2024-02-09, 1402/11/20
Expected recruitment end date
2024-04-18, 1403/01/30
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title

"The effects of palliative care on anxious thoughts and life expectancy in patients with heart failure

Public title

"The effects of palliative care on anxious thoughts and life expectancy in patients with heart failure referred to the heart departments hospitals"

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Age over 18 years Having heart failure Ability to understand and speak Persian Ability to answer questionnaire questions

Exclusion criteria:

Not participating in more than two training sessions Not answering more than a third of the questions Sensory disorders such as vision and hearing problems that affect learning

Age

From **18 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **80**

Randomization (investigator's opinion)

Randomized

Randomization description

The samples will be selected by continuous sampling and the patients will be placed in 2 control and test groups by Block Balanced Randomization method. Allocation sequence will be done using the free web system http://www.randomization.com/.In this way, the number of samples in each block is determined by 4 people and the letter A will be considered for the intervention group and the letter B will be considered for the control group. And finally, by confirming the creation of the allocation sequence in the above system for 20 blocks, the allocation sequence for 80 samples will be created by combining the letters A and B. Finally, the cards containing the blocks will be placed inside the governor's envelope, and as a result, the concealment of the allocation will be considered and respected. Based on the qualified samples, an envelope will be removed by the researcher using random sampling method and finally the method of random allocation of research samples will be determined.

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Kerman University of Medical Sciences

Street address

Kerman University of Medical Sciences, The beginning of Haft Bagh Road, Kerman

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Postal code

7616913555

Approval date

2023-12-11, 1402/09/20

Ethics committee reference number

IR.KMU.REC.1402.348

Health conditions studied

1

Description of health condition studied

Heart Failure

ICD-10 code

I50

ICD-10 code description

Heart failure

Primary outcomes

1

Description

Anxious thoughts

Timepoint

Anxiety thoughts will be measured before the intervention and immediately after the intervention.

Method of measurement

Wells Anxious thoughts Scale

2

Description

life expectancy

Timepoint

Life expectancy will be measured before the intervention and immediately after the intervention.

Method of measurement

Schneider life expectancy scale

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: The intervention group includes patients with heart failure referred to the heart departments of hospitals affiliated to Kerman University of Medical Sciences. The intervention group receives the educational protocol along with routine care. The educational protocol of the study includes a two-week palliative care program in the form of one-hour training sessions, four times a week. The educational content is narrated by experts in the field of palliative care, and will be implemented by a researcher who is trained through a supervisor who is a professor of palliative medicine. In the first week of the sessions, when the patients are in the hospital, it will be performed individually for the patients. At the time of discharge, they are asked to go to the hospital in order to receive the continuation of the palliative care program on certain days, and the continuation of the educational sessions in the second week for the patients is carried out in the patient education center in groups (small groups) in coordination with the relevant hospitals. The content of the program is mostly related to the aspects of increasing the awareness and knowledge of patients in relation to their disease, increasing the aspects of self-care, techniques to control anxiety and anxious thoughts, and ways to increase self-confidence. During the intervention, the researcher will evaluate, educate and counsel the patients in the first session. Patients' knowledge and ability in self-management, family support system, and their educational and counseling needs, including heart failure symptoms and self-care, will be evaluated. An educational brochure will also be provided to patients. During the first week, when the meetings are held individually, the guidelines for heart failure will be explained and the researcher will provide emotional support to the patients by encouraging them to express their feelings. She will actively listen to the patient's responses by encouraging them to express their feelings and it will support them in taking small steps to solve the problem. And in the second week, the meetings are in groups , It will be explained in relation to the solutions of having a healthy lifestyle and strengthening your spirit, and how to control and manage the disease and strengthen self-confidence.

Category

Behavior

2

Description

Control group: Usual care in heart failure will be provided to patients.

Category

Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center

Kerman University of Medical Sciences

Full name of responsible person

Mehdi Ahmadinejad

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Kerman University of Medical Sciences, Haft Bagh Road first، Kerman

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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Grant name

Deputy of research and technology, Kerman University of Medical Sciences

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Kerman University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Academic

Person responsible for general inquiries

Contact

Name of organization / entity
Kerman University of Medical Sciences

Full name of responsible person
Rezvan Askarpour

Position
Masters student

Latest degree
Bachelor

Other areas of specialty/work
Nursery

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available

Study Protocol
Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available

Analytic Code
Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available